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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/854,786

05/14/2001

Joydeep Lahiri

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7590

08/23/2002

CORNING INCORPORATED
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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/23/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,786

Applicant(s)

LAHIRI ET AL.

Examiner

My-Chau T. Tran

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 33-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 & 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (Claims 1-32 and 51) in Paper No. 11 is acknowledged.

2. Claims 33-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 11.

3. This application contains claims 33-50 drawn to an invention nonelected without traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

5. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable

Art Unit: 1641

drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-32 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not clearly and adequately describe the invention and therefore the scope of the invention would encompass the prior art. Throughout the specification the inventions disclosed can be considered prior art. For example the surface binding lipid membrane that incorporate a protein is known in the art (pg 1-3 and 13-15 of the specification). The γ -aminopropyl-silane coated slide, which is being claimed in claim 19, is commercially available (pg. 11, lines 24-26 of the specification). The specification does not enable any person skilled in

Art Unit: 1641

the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Where is the point of novelty in the invention?

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-32 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “biological membrane” is vague and confusing because the “biological membrane” as defined by the specification incorporates both synthetics such as liposomes and vesicles and naturally occurring membranes (pg. 13, lines 26-31). But based on [~]conventional definition of the “biological membrane”, a biological membrane is a membrane with a biological component such as specific binding. This type of component is not found in the synthetic membranes. Therefore how would such a biological membrane function for the purpose of the invention?

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 6-9, 11-14, 20-21, and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bieri et al. (*Nature Biotechnology*, 1999, 17(11):1105-1108).

Bieri teaches a patterned self assembled membrane bound sensor chip (Abstract; fig. 1). The sensor is comprised of a gold surface, a membrane layer that is bound to the surface through a biotinylated thiols, and G protein coupled receptors are incorporated in the membrane (pg. 1106, left col. lines 16-29; pg. 1108, left col., lines 23-40; fig. 1). The sensor chip of Bieri anticipates the claimed invention.

12. Claims 1-6, 8-9, 11-14, 20-21, and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (US Patent 5,756,355).

Lang teaches a bilayer lipid membrane sensor comprising a gold recording surface, a thiolipid layer that is anchored to the gold surface by self-assembly through an oxyethylene chain (spacer arm), an aqueous layer is trapped between the gold surface and the thiolipid layer due to the length of the spacer arm, and a second lipid layer of phospholipid (Abstract; col. 2, lines 54-67). The lipid bilayer contains a small number of biosensitive molecules (col. 1, lines 31-37). The number (n) of oxyethylene group is from 2-10 (col. 1, lines 55-63; col. 3, lines 1-8). The lipid membrane sensor incorporates a membrane protein receptor, which can selectively bind drugs, protein, viruses, etc. from the surrounding medium, such as ion channels, G protein coupled receptors, and other receptors known in the art (col. 4, lines 57-67 to col. 5, lines 1-13). The bilayers lipid membrane sensor of Lang anticipates the claimed invention.

Art Unit: 1641

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 7, 10, 15-19, 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (US Patent 5,756,355) in view of Patton (US Patent 4,933,285).

The biological membrane bound sensor of Lang is applied for the reasons discussed above.

Lang differs from the claimed invention by failing to include the plastic or glass substrate and coating material such as gamma-aminopropylsilane. However, Lang discloses the use of silicon electrodes coated with gold (col. 8, lines 28-49).

Patton discloses a structure comprising monolayers of polymeric linkages used as biochemical sensors (col. 1, lines 10-17). The substrate includes inorganics such as silicon or silicon oxide, natural and synthetic polymers, and metals such as gold (col. 3, lines 35-68 to col. 4, lines 1-6). The polymeric linkage is bifunctional with functional groups such as amino groups, or alcohols (col. 2, lines 22-38). The silicon oxide layer is covalently linked to gamma-aminopropylsilane (col. 4, lines 7-25). The polymeric linkage would provide enhanced stabilities of the immobilized biomolecules (col. 15, lines 8-20).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include in the biological membrane bound sensor of Lang the plastic or glass substrate and coating material such as gamma-aminopropylsilane as taught by of Patton because the polymeric linkage would provide enhanced stabilities of the immobilized biomolecules and the choice of substrate such as plastic or glass would provide the advantage of economy and convenience.

The features of remaining dependent claims are either specifically described by the reference (e.g. glass or silane compound), or constitute obvious variations in parameters which are routinely modified in the art (e.g. contact angle), and which have not been described as critical to the practice of the invention.

17. Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (US Patent 5,756,355) in view of Plant (*Langmuir*, **1999**, 15(15):5128-5135).

The biological membrane bound sensor of Lang is applied for the reasons discussed above.

Lang differs from the claimed invention by failing to include the thioalkyl compound.

Plant disclosed hybrid bilayers containing thiol-derivatized alkane moieties plus natural lipids providing a biomimetic matrix that permits the successful reconstruction of membrane protein activity (Abstract). The alkanethiol is a self assembled monolayer (pg. 5128, right col., lines 11-21; fig.1). The alkanethiols would provide the distinct advantage of a complete hydrophobic layer at the metal surface and the driving force for the formation of complete bilayers (pg. 5128, right col., lines 28-38 to pg. 5129, left col., lines 18-37).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include in the biological membrane bound sensor of Lang the thioalkyl compound as taught by of Plant because the thioalkyl compound would provide the distinct advantage of a complete hydrophobic layer at the metal surface and the driving force for the formation of complete bilayers.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
August 20, 2002

Mary E. Ceperley
MARY E. CEPERLEY
PRIMARY EXAMINER
AU1641